UNITED STATES DISTRICT COURT
DISTRICT OF NEW HAMPSHIRE

Sarah A. Katz, both Individually and as Administratrix of the Estate of Chevy Katz, f/k/a Chevy Wilde, Plaintiff, v. Michael J. O'Connell, M.D., Nita Grover, M.D., Hugh Cochran, APRN, CRNA, Michael J. O'Connell d/b/a Paincare Centers, Michael J. O'Connell d/b/a Dr. O'Connell's Pain Care Center, Dr. O'Connell's Pain Care Centers, Inc., Dr. O'Connell's Pain Care Centers, Inc., a/k/a Pain Care Centers, Inc., Defendants.	Civil Action No. _____ **COMPLAINT FOR DAMAGES AND DEMAND FOR JURY TRIAL**

NOW COMES the Plaintiff, Sarah A. Katz, both Individually and as Administratrix of the Estate of Chevy Katz, f/k/a Chevy Wilde, by and through her attorneys, Rilee & Associates, P.L.L.C., and respectfully submits the following Complaint for Damages and Demand for Jury Trial, stating in support thereof as follows:

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I. INTRODUCTION

1. Beginning in 2012, a widespread outbreak of fungal meningitis in more than 20 states has now caused scores of deaths as of the time of the filing of this Complaint. At a minimum, over 750 people have been diagnosed with serious illnesses. This preventable outbreak originated from medication which was improperly compounded, sterilized, tested, packaged, marketed, labeled, and distributed by the now bankrupt New England Compounding Pharmacy, Inc. d/b/a "New England Compounding Center"("NECC"). The medication was then acquired, dispensed, prescribed and administered by the various defendants named herein.

2. The United States Food and Drug Administration ("FDA") and the Centers for Disease Control and Prevention ("CDC") have confirmed the presence of fungus in unopened vials of NECC's methylprednisolone acetate ("MPA"). The FDA and CDC have also identified

bacteria and/or fungus present in NECC-supplied preservative-free injectable betamethasone, preservative-free triamcinolone, and cardioplegia solution. Some of the contaminants identified in these products are known to cause human disease.

3. Multiple vials of MPA, along with other medications compounded at the NECC facilities, were recalled, but the recall was too late for the Plaintiff, and for many others who suffered serious and catastrophic injuries or death from one of the largest iatrogenic epidemics in United States history.

4. No one disputes that the contaminated products that caused these horrific injuries were made by NECC. No one seriously disputes that the deplorable conditions at NECC contributed to this outbreak. But the story does not begin or end with NECC: multiple actors contributed to the chain of events that led to this tragedy.

5. Not one person would have developed a fungal infection if hospitals, clinics, healthcare facilities, and/or physicians had not given these contaminated medications to patients. Apparently around 75 hospitals, clinics, healthcare facilities and/or physicians in at least 20 states injected patients with contaminated drugs from NECC. These clinics ordered these medications (often with fake or no patient names), purchased the contaminated medications, received the contaminated medications, stored the contaminated medications, and injected the contaminated medications into patients – often dozens of patients. Clinics often disregarded the prevailing industry guidelines and pharmacy regulations requiring individual medications to be compounded in response to receiving a prescription for a particular patient. Clinics did so out of convenience and greed: ordering large doses of injectable steroids in bulk allowed them to stock their shelves without going through the “hassle” (but really safeguard) of identifying particular

patients who would receive the drug. And NECC's price for MPA was, generally, lower than the prices for brand name methylprednisolone acetate (DepoMedrol) manufactured by Pfizer.

6. A multidistrict litigation ("MDL") is currently pending in the United States District Court-District of Massachusetts (In Re: New England Compounding Pharmacy, Inc. Products Liability Litigation, Case No: 1:13-md-2419-FDS). The Court has appointed a Plaintiffs' Steering Committee ("PSC") to guide the MDL proceeding.

7. This Complaint does not include allegations against NECC, and other related parties, Ameridose LLC, Alaunus Pharmaceuticals, Inc., Medical Sales Management, Inc., Medical Sales Management SW, Inc., GDG Holdings, Barry Cadden, Lisa Conigliaro Cadden, Doug Conigliaro, Carla Conigliaro, Greg Conigliaro, or Glenn Chin (hereafter "Affiliated Defendants"), nor does it name entities that have agreed to mediation pursuant to the Court's Order on mediation (Document 502) filed within the MDL proceedings. Plaintiff reserves the right to amend this Complaint to add allegations and claims against individuals or entities currently omitted and to add or amend allegations against Defendants named herein based, in part, on further discovery

8. On December 21, 2012, NECC filed a petition for Bankruptcy protection under Chapter 11 of the Bankruptcy Code: In re: New England Compounding Pharmacy, Inc., Debtor, United States Bankruptcy Court for the District of Massachusetts Case no. 12:19882 HJB. A United States Trustee was subsequently appointed to administer the Bankruptcy Estate.

9. This Complaint also does not include claims against UniFirst Corporation, UniFirst Corporation d/b/a UniClean Cleanroom Services ("Unifirst") or Liberty Industries, Inc. as these entities have entered into settlement in connection with the proposed bankruptcy plan in NECC's bankruptcy, and statutes of limitations have been tolled against some of those

defendants, allegations concerning those defendants remain in the Second Amended Master Complaint filed in the MDL as outlined above.

10. Decedent Chevy Katz, f/k/a Chevy Wilde was injected and administered contaminated and tainted MPA[1], and/or the injection/administration was or should have been supervised by, Michael J. O'Connell, M.D., Nita Grover, M.D., and/or Hugh Cochran APRN, CRNA, Michael J. O'Connell d/b/a PainCare Centers, Michael J. O'Connell d/b/a Dr. O'Connell's Pain Care Center, Dr. O'Connell's Pain Care Center, Dr. O'Connell's Pain Care Centers, Inc., Dr. O'Connell's Pain Care Centers, Inc. a/k/a Pain Care Centers, Inc., and/or Pain Care Centers (collectively the "O'Connell Defendants").

11. Plaintiff seeks compensatory, enhanced, and exemplary damages, and all other available remedies as a result of injuries caused by the contaminated MPA, including death of Decedent Chevy Katz, f/k/a Chevy Wilde, and her loss of consortium individually. Plaintiff makes the following allegations based upon her personal knowledge and upon information and belief, as well as upon her attorneys' investigative efforts.

II. JURISDICTION AND VENUE

12. This Court has subject matter jurisdiction over the parties pursuant to 28 U.S.C. §1334(b) because, as described herein, each claim asserted is related to a pending bankruptcy previously filed by NECC as referenced in paragraph 8, a case under Title 11, and the outcome of this proceeding could have some effect on the Bankruptcy Estate.

13. Plaintiff, through Decedent Chevy Katz, f/k/a Chevy Wilde, filed the required Proof of Claim Form and PITWD Addendum (Personal Injury or Wrongful Death Claim Information Form) in the pending Bankruptcy action referred to in paragraph 8 above.

[1] Decedent was also injected with Triamcinolone which, while discovery is ongoing, upon information and belief, was manufactured by NECC and was potentially contaminated as well.

14. The O'Connell Defendants have not, upon information and belief, filed claims in the bankruptcy proceedings.

15. Upon information and belief, NECC has express contractual indemnification obligations with other NECC related parties including, Barry Cadden, Gregory Conigliaro, Lisa Cadden, Carla Conigliaro, Douglas Conigliaro, Glen Chin, GDCMSM and MSMSW ("Related Parties"). Some, if not all of the aforementioned individuals and entities are insured under NECC insurance policies. NECC and the Related Parties all have contribution, indemnification, and/or other reimbursement claims against each other.

16. Adversary proceedings seeking recovery of damages for the benefit of the Bankruptcy Estate and its unsecured creditors have been filed in the NECC bankruptcy against several of the related parties.

17. Lawsuits alleging death or injury based on contaminated MPA have been filed around the country. On February 12, 2013, the Judicial Panel on Multidistrict Litigation (MDL No. 2419) issued an order under 28 U.S.C. § 1407 transferring various federal-court proceedings to the United States District Court for the District of Massachusetts for coordinated or consolidated pre-trial proceedings ("MDL Court"). The transferred actions are pending in the MDL Court in the Multi-District Litigation action titled In re: New England Compounding Pharmacy Inc., Products Liability Litigation, United States District Court District of Massachusetts, MDL No. 1:13-md-2419-FDS. The transferred cases have been assigned to the Honorable Rya W. Zobel, United States District Judge, for pre-trial proceedings and coordination. This case is a related case to those cases transferred to the MDL Court and, subject to transfer per order of the MDL Court relating to transfer of cases, related to the NECC MDL and Chapter 11 Bankruptcy.

18. Venue is proper under 28 U.S.C. § 1391, as a substantial amount of activity giving rise to the claims occurred in this District.

19. Venue lies initially in this District Court as Plaintiff and defendants are citizens of New Hampshire and reside or are headquartered in this District, and this court has *in personam* jurisdiction over all defendants under the jurisdictional laws of New Hampshire based on the circumstances plead below.

III. PARTIES

Plaintiff

20. Plaintiff Sarah A. Katz, is a citizen and resident of the State of New Hampshire, is Administratrix of the Estate of Chevy Katz, f/k/a Chevy Wilde, her husband, and resides in Portsmouth, New Hampshire 03801. Decedent Chevy Katz, f/k/a Chevy Wilde (hereinafter "Decedent") suffered injury, distress, and death as a direct and proximate result of being injected with and administered the contaminated and tainted MPA and potentially contaminated Triamcinolone on one or more occasions, beginning on or about July 10, 2012 while a patient of the O'Connell Defendants. Plaintiff individually has suffered loss of consortium related to the injury, distress, and death of Decedent.

The O'Connell Defendants

21. The CDC has identified the O'Connell Defendants as having received recalled lots of MPA from NECC.

22. Dr. O'Connell's Pain Care Centers, Inc. and Dr. O'Connell's Pain Care Centers, Inc. a/k/a Pain Care Centers, Inc. are New Hampshire corporations with an address of 255 Route 108, Somersworth, County of Strafford, New Hampshire 03878.

23. Defendant Michael J. O'Connell, M.D. (hereinafter "O'Connell") is a citizen and resident of New Hampshire and held himself out to be a physician licensed to practice medicine in the State of New Hampshire, and as being a skilled and knowledgeable physician engaged in the practice of medicine and in particular, in the specialties of anesthesiology and pain medicine. O'Connell, at all times material herein, was employed by, associated with and/or was an owner, Chief Executive Officer (CEO), operator, supervisor, member or shareholder of the medical practices and O'Connell Defendants known as Pain Care Centers, Dr. O'Connell's Pain Care Center, Dr. O'Connell's Pain Care Centers, Inc. and Dr. O'Connell's Pain Care Centers, Inc. a/k/a Pain Care Centers, Inc. at 255 Route 108, Somersworth, New Hampshire, 03878. In or about January 2012 O'Connell voluntarily surrendered his license to practice medicine in the State of New Hampshire as a result of disciplinary proceedings commenced by the New Hampshire Board of Medicine (In the Matter of Michael J. O'Connell, M.D., No. 7690). Upon information and belief, and at all times relevant herein, O'Connell provided treatment to Plaintiff and supervised and/or directed John Kane, APRN, CRNA.

24. Defendant Nita Grover, M.D. (hererinafter "Grover") is a citizen and resident of New Hampshire and a physician licensed to practice medicine in the State of New Hampshire, holding herself out to the public as being a skilled and knowledgeable physician engaged in the practice of medicine and in particular, in the specialties of anesthesiology and pain medicine. Grover, at all times material herein, was employed by and/or associated with the medical practices and O'Connell Defendants known as Pain Care Centers, Dr. O'Connell's Pain Care Center, Dr. O'Connell's Pain Care Centers, Inc. and Dr. O'Connell's Pain Care Centers, Inc. a/k/a Pain Care Centers, Inc. at 255 Route 108, Somersworth, New Hampshire, 03878. Upon

information and belief, and at all times relevant herein, Grover provided treatment to Decedent and supervised and/or directed Hugh Cochran, APRN, CRNA.

25. Defendant Hugh Cochran, APRN, CRNA (hereinafter "Cochran") is a New Hampshire resident and an Advanced Registered Nurse Practitioner who, upon information and belief, is supervised by O'Connell and/or Grover and held himself out to the public as being skilled and knowledgeable concerning the practice of medicine and in particular, in the specialties of anesthesiology and pain medicine. Cochran, at all times material herein, was employed by and/or associated with the medical practices and O'Connell Defendants as listed above at 255 Route 108, Somersworth, New Hampshire, 03878. Cochran, under the supervision of O'Connell and Grover, is the individual who injected Decedent with the tainted MPA on or about July 10, 2012.

26. The O'Connell Defendants were responsible for procuring and administering NECC Contaminated Drugs. Upon information and belief, the O'Connell Defendants injected or administered the NECC Contaminated Drugs to Plaintiff. At all relevant times, the physicians, staff, agents and employees of the above-named O'Connell Defendants were acting within the course and scope of their employment and/or agency.

27. At all times relevant herein, the O'Connell Defendants treated patients for consideration, including Decedent.

IV. FACTUAL BACKGROUND

A. The Conigliaro Family Businesses.

1. Conigliaro Industries' Recycling Plant.

28. In 1990, Gregory Conigliaro opened Conigliaro Engineering in an old industrial building on Waverly Street in Framingham, Massachusetts. In 1991, the company incorporated

under the new name Conigliaro Industries, Inc. and began recycling plastic, metal, glass, and paper. It made money by converting detergent bottles into recycling bins, molded Styrofoam lunch trays into flower pots, and plastic computer casings into pothole filler.

29. Early on, Gregory Conigliaro branched out into real estate, starting GDC Holdings, Inc. and GDC Properties Management, LLC.

30. In April 2003, Conigliaro Industries opened the first U.S. commercial plant that shreds and recycles mattresses, including polyurethane foam parts. The mattress recycling operation was planned and developed by Tony Conigliaro, the Vice President of Engineering and Gregory's father. The company built a 2,500 square foot mattress shredding facility located next to its 90,000 square foot plant on a seven acre parcel in Framingham. The company also earmarked another 5,000 square feet of its main factory space for the venture and utilized its 30 docks for the operation.

31. Old used mattresses from schools, prisons, and hospitals are put through a giant shredder that separates the polyurethane foam from the springs and wood frame and bales the foam. Gregory Conigliaro claimed that the company (Nationwide Foam, Inc., 703 Waverly Street, Framingham, Massachusetts) could recycle mattresses at the rate of one each minute.

32. Conigliaro Industries touted itself as a pioneer in the field of "Total Recycling" and recycles over 150 different materials, including rubber, plastics, and metal. The business operates out of an 88,000 square foot facility located at 701 Waverly Street, in the large Framingham complex owned by Gregory Conigliaro's real estate companies, GDC Holdings, Inc. and/or GDC Properties Management, LLC. The Framingham Board of Health has received a number of complaints about the mounding trash piles tucked behind the Waverly Street strip mall.

Figure 1: Trash behind 701 Waverly Street[3]

"Sterility Found Lacking at Drug Site in Outbreak," N.Y. TIMES (Oct. 23, 2012) (available at http://www.nytimes.com/2012/10/24/health/sterility-found-lacking-at-drug-site-in-meningitis-outbreak.html?pagewanted=all&_r=0),.

Figure 2: Google Earth image of 701 Waverly St.

2. Gregory Conigliaro, Barry Cadden, and Douglas Conigliaro founded NECC.

33. In 1998, well after the Conigliaro recycling facility and real estate companies were up and running, the Conigliaro family branched out into pharmaceutical compounding. Gregory Conigliaro's sister, Lisa Conigliaro Cadden, and her husband, Barry Cadden, were both pharmacists. Gregory Conigliaro and Barry Cadden co-founded New England Compounding Pharmacy, Inc., known as New England Compounding Center ("NECC"). NECC opened in the same Waverly Street building that housed the recycling plant and real estate businesses. Its front door is immediately next to the front door to Nationwide Foam.

34. Another Conigliaro brother, Dr. Douglas Conigliaro, was an anesthesiologist with substantial litigation in his past. He allegedly punctured a 64-year-old woman's spine during a 1995 operation to insert a pump to deliver painkillers. The woman became paralyzed and died two years later. The suit ultimately settled for $1 million and Douglas Conigliaro was fined $10,000 by the Florida state medical board.

35. Douglas Conigliaro's wife, Carla Conigliaro initially owned sixty-five percent (65%) of NECC. Carla Conigliaro (a nurse) was originally listed as the company's president. Douglas Conigliaro was personally involved with NECC from the beginning and continued to be involved until NECC shut its doors. Because of his previous legal troubles, he was careful to conceal his involvement. He also ordered others at NECC and the Affiliated Defendants to conceal his involvement.

36. Barry Cadden ran NECC, typically wearing scrubs to work. Cadden held positions as the President, Chief Pharmacist, and Director of NECC.

37. Gregory Conigliaro provided financial advice and usually wore a shirt and tie. Lisa Conigliaro Cadden was a board member and worked as a pharmacist at NECC.

B. Background on Compounding Pharmacies.

38. According to the FDA, traditional compounding is the extemporaneous combining, mixing, or altering of ingredients by a pharmacist in response to a physician's prescription to create a medication tailored to the specialized needs of an individual patient. Traditional compounding typically is used to prepare medications that are not available commercially, such as a drug for a patient who is allergic to an ingredient in a mass-produced product, or diluted dosages for children.

39. NECC's webpage claimed compounding allows doctors to prescribe prescription drugs that are "no longer manufactured, persistently backordered because of production shortages, not commercially available in the dosage form the patient needs (e.g., preservative free)."

40. In Massachusetts, compounding pharmacies must have a prescription for an individual patient in order to create a drug.

41. Compounding pharmacies generally follow testing guidelines established by the U.S. Pharmacopeia (USP), a nonprofit private group that develops standards of drug quality. According to an industry group, the International Academy of Compounding Pharmacists, adherence to the USP standards is expected. Some Massachusetts compounding pharmacies, including Microtest Laboratories, typically test more than the number of samples required by the USP standards to confirm sterility.

42. Compounding industry standards were created for pharmacists making small batches of medicines for individuals, not for the commercial production of large batches.

C. The Risks of Pharmacy Compounding.

43. The serious risks of pharmacy compounding were the subject of considerable public discussion in the pharmacy community and the medical community before the NECC meningitis outbreak.

44. In 2002, the CDC published a report regarding at least two cases of fungal meningitis arising from contaminated medication used in epidural injections. The report concluded that "purchasers of pharmaceuticals should determine if supplies are provided from a compounding pharmacy that . . . follows appropriate measures to ensure that injectable products are free of contamination."

45. On March 24, 2005, USA Today published a front page article with the following headline: "Safety concerns grow over pharmacy-mixed drugs." That article discussed growing concern over the fact that drugs produced in bulk by compounding pharmacies are not FDA approved and are not subject to the same oversight as drugs produced by pharmaceutical companies.

46. In 2006, the FDA conducted a survey of compounded drug products. They collected 36 samples from compounding pharmacies across the United States during unannounced visits. Twelve of the 36 samples (33%) failed analytical testing. The FDA survey concluded "poor quality compounded drugs are a serious public health concern, as improperly compounded products have been linked to grave adverse events, including deaths."

47. In May 2007, the FDA published an article titled: "The Special Risks of Pharmacy Compounding." That article highlighted numerous adverse events involving compounded products. It also warned of the emergence of large scale compounding operations that were clearly operating outside the bounds of traditional compounding practice.

48. In 2010, the FDA posted an educational video on YouTube regarding concerns over the quality of compounded drugs.

49. On November 5, 2010, the American Society of Anesthesiologists, the American Society of Health-System Pharmacists ("ASHP") and other medical societies published a joint report regarding drug shortages. That report included an article written by the ASHP stating as follows:

> *Compounding pharmacies have also pursued the production of drugs that are in short supply. Caution is warranted because preparations from these pharmacies may not meet applicable state or federal standards (e.g., United States Pharmacopeia chapter 797 or FDA labeling requirements). The sources of raw materials used by compounding pharmacies have been questioned, and apparent lapses in quality control have resulted in serious patient injury, including death.. . .Compounding pharmacies may also present patient risks; several deaths have been associated with improperly sterilized compounded products.*

50. In May 2012, the CDC published a report regarding fungal infections arising from medications obtained from a compounding pharmacy. That report advised that "contamination of compounded sterile preparations has caused outbreaks. Since 1990, FDA has learned of approximately 200 adverse events associated with 71 compounded products."

D. Meningitis.

51. Meningitis is an infection of the membranes covering the brain and spinal cord (meninges). Primary symptoms include: fever, chills, altered mental status, nausea, vomiting, sensitivity to light (photophobia), severe headache, and neck stiffness. Meningitis is typically diagnosed by lumbar puncture (spinal tap) that collects spinal fluid (cerebrospinal fluid). The fluid is then tested to determine the infection's exact cause for an appropriate course of treatment. When a lumbar puncture is not possible, a diagnosis may be presumed based on the constellation of symptoms. Complications and risks from meningitis include: brain damage,

buildup of fluid between the skull and brain (subdural effusion), hearing loss, hydrocephalus, and seizures.

52. Meningitis can be caused by several factors including bacteria, viruses, and fungus. Fungal meningitis is rare and people with weak immune systems are at a higher risk of contraction.

53. Meningitis is an infection that usually spreads through the blood to the spinal cord. It is caused by the introduction of a bacteria, virus, or fungus into the central nervous system or from an infected body site infection next to the central nervous system. Primary symptoms include: fever, altered mental status, nausea, vomiting, sensitivity to light (photophobia), headache, and stiff neck. Death may result from fungal meningitis.

54. The typical incubation period for contracting fungal meningitis from a tainted steroid is one to four weeks after injection, though it can be far longer and symptoms can be mild in nature. As with any variety of meningitis, it is important to perform a lumbar puncture (spinal tap) to collect and test spinal fluid (cerebrospinal fluid) and determine the exact type of fungus for an appropriate course of treatment. Appropriate laboratory tests may vary depending on the type of fungus suspected. Treatment of fungal meningitis typically requires long courses of high dose antifungal medications but treatment length can vary depending on the state of the immune system and type of fungus.

E. The Outbreak and Its Aftermath.

55. On September 21, 2012, the CDC was notified by the Tennessee Department of Health ("TDH") of a patient with the onset of meningitis following an epidural steroid injection. It was later determined that the patient had fungal meningitis.

56. On September 24, 2012 the TDH notified the Massachusetts Department of Public Health ("MDPH") about a cluster of six fungal meningitis cases with symptoms that began between July 30 and September 18, 2012. These patients all received injections of preservative-free MPA, compounded at NECC in Framingham, Massachusetts.

57. In September 2012, the TDH identified nine cases of fungal meningitis following injection of MPA, compounded at NECC. All nine patients had received one or more injections from three lots of MPA (lot numbers 05212012@68, 06292012@26, and 08102012@51).

F. FDA and MDPH Begin Investigating NECC.

58. The MDPH, Board of Registration in Pharmacy, and Bureau of Infectious Diseases convened a multi-agency meeting with the TDH, the CDC, the FDA, and NECC. At the demand of MDPH staff, Barry Cadden and Gregory Conigliaro provided documentation of facilities that received medications from three lots of MPA suspected as linked to the fungal infections. According to those lists, the suspected lots contained 17,676 doses and were distributed in 23 states.

59. According to the CDC, *Exserohilum rostratum* has been identified as one of the predominant pathogens in the multistate outbreak of fungal meningitis and other fungal infections associated with contaminated MPA.

60. On September 26, 2012 NECC recalled three lots of preservative-free MPA: Lot #05212012@68, BUD 11/17/2012; Lot #06292012@26, BUD 12/26/2012; and Lot #08102012@51, BUD 2/6/2013. Approximately 3,000 doses were quarantined or returned through recall. This meant that approximately 14,000 people received contaminated injections. NECC faxed the recall notices to the facilities that had received the contaminated lots beginning on September 26, 2012.

61. On the same day, the MDPH began its investigation of NECC's facility. When MDPH arrived at NECC, investigators found NECC employees cleaning compounding areas and conducting environmental testing. The investigators also detected signs of black contamination in the compounding areas.

62. Before arrival of investigators, NECC had terminated many of its staff. After September 26, 2012, the majority of NECC employees were no longer on site.

63. On October 1, 2012 MDPH and FDA began a joint investigation of NECC. Investigators were shown examples of MPA products that were labeled as patient-specific. However, NECC did not have individual prescriptions from specific clinics. As a result, upon information and belief, NECC used lists of patients and/or orders generated by clinical facilities and provided to NECC to obtain the product without individual, specific, or legitimate patient names.

64. MDPH issued a formal Quarantine Notice pursuant to M.G.L. c. 94C §§13 and 189A, and M.G.L. c. 112 §§ 30 and 42A, in accordance with the CDC's epidemiological work. The Notice directs that all raw materials, all non-sterile and sterile products located at NECC used in the compounding of MPA and all inventory on the premises prepared for dispensing and stored at the pharmacy should be quarantined and not disposed of without MDPH's approval.

65. MDPH and FDA observed visible black particulate matter in sealed vials of purportedly sterile MPA returned to NECC. Inconsistencies in sterilization of processed materials were identified through review of NECC's records. The board voted to obtain a Voluntary Surrender of NECC's license or to initiate action to issue a Temporary Order of Summary Suspension.

G. NECC Surrenders Its Pharmacy License and Recalls All of Its Products.

66. On October 3, 2012, NECC surrendered its pharmacy license in Massachusetts. It ceased all production and initiated recall of all MPA and other drug products prepared for injections in and around the spinal cord (known as intrathecal administration).

67. On October 5, 2012, MDPH and FDA investigators noted visible contaminants in additional sealed recalled vials of MPA. MDPH and FDA issued a nationwide alert to providers and facilities across the country, informing them about the particulate matter.

68. On or about October 5, 2012, the New Hampshire Board of Pharmacy, based on the Massachusetts Board's actions, suspended NECC's Non-Resident Permit and scheduled a hearing to determine whether or not NECC had engaged in professional misconduct contrary to NHRSA 318:29, II and/or RSA 318:30-a, and/or Ph. 202.03(d).

69. On October 6, 2012 NECC, in conjunction with the FDA, CDC, and Massachusetts Board of Registration in Pharmacy's investigation, recalled all products currently in circulation that were compounded at and distributed from its facility in Framingham, Massachusetts "due to the potential risk of contamination."

70. In NECC's October 6, 2012 press release, NECC advised that it was "notifying its customers of this recall by fax[,]" and that "[c]linics, hospitals and healthcare providers that have product which is being recalled should stop using the product immediately, retain and secure the product, and follow instructions contained in the fax notice."

71. On or about October 14, 2012, NECC voluntarily surrendered its Non-Resident Permit in the State of New Hampshire.

H. FDA, Massachusetts Board of Pharmacy's Findings.

72. MDPH obtained documentary evidence (including photographs), reviewed and obtained copies of NECC Standard Operating Procedures, made observational findings, reviewed and obtained copies of all policies and procedures, reviewed batch records and interviewed NECC staff. The FDA conducted product testing and took environmental samples of various areas of the facility to test for contaminants.

73. From the beginning of their investigation, the MDPH and FDA identified "serious deficiencies and significant violations of pharmacy law and regulations that clearly placed the public's health and safety at risk." The FDA reported that it had detected fungal contamination by microscopic examination of particulate matter taken from a sealed vial of MPA collected from NECC. The FDA also noted that "foreign material" had also been observed in other vials produced by NECC that were collected by FDA during an inspection. FDA further stated that it was in the process of further identifying the fungal contaminant and conducting microbial testing.

I. MDPH's Preliminary Findings.

74. On October 23, 2012, the MDPH released its preliminary investigation findings.

75. NECC distributed two of the recalled lots of MPA (preservative free) 80 MG/ML before receiving results of sterility testing. Lot 06292012@26 was prepared on June 29, 2012. Final sterility testing was completed on July 17, 2012. Two shipments of product were sent out before the final sterility tests results were received. Lot 08102012@51 was prepared on August 10, 2012. Final sterility testing was completed on August 28, 2012. At least eleven shipments of product were sent out before the final sterility test results were received. NECC's records claim

that these sterility tests found no contamination, but the MDPH questioned whether NECC's sterility testing methods were adequate.

76. The MDPH observed visible black particulate matter in several recalled sealed vials of MPA from Lot 08102012@51.

77. NECC did not follow either the proper USP 797 autoclaving sterilization procedure or its own standards operating procedures. The MDPH noted NECC's systemic failure to keep products in the autoclave for the required minimum 20-minute sterilization period necessary to ensure product sterility.

78. MDPH found that NECC distributed large batches of compound "sterile" products directly to facilities apparently for general use rather than requiring a prescription for an individual patient, in violation of its state pharmacy license.

79. NECC did not have patient-specific prescriptions from an authorized practitioner when compounding and dispensing medication, as required by state law.

80. NECC did not conduct patient-specific medication history and drug utilization reviews, as required by regulations.

81. The clean rooms used to compound the drugs were not appropriately sealed, allowing contaminants to infiltrate the room, and exposing the drugs to contamination.

82. Powder hoods, intended to protect pharmacists from inhaling substances during medication preparation within the sterile compounding area were not thoroughly cleaned pursuant to USP 797 or pursuant to NECC standard operating procedures. Residual powder was visually observed, which could lead to contamination of compounded medications.

83. "Tacky mats" used to trap dirt, dust, and other potential contaminants from shoes prior to clean room entry were visibly soiled with debris, in violation of USP 797.

84. A leaky boiler next to the clean room created an environment susceptible to contaminant growth, including a pool of standing water.

J. FDA's Initial Findings and Form 483 Report.

85. On October 18, 2012, the FDA released definitive laboratory confirmation of the presences of fungal contaminants in sealed vials of MPA in a suspect lot prepared by NECC.

86. On October 26, 2012, the FDA released a copy of the FDA Form 483 issued to NECC. The FDA issues a 483 at the end of an inspection when the investigators believe that they observed conditions or practices that indicate violations of the Food, Drug, and Cosmetic Act or attendant regulations.

87. The FDA observed and has since confirmed contaminated products and listed a number of observations regarding conditions in the Clean Room 2 at NECC's Framingham facility.

88. During an October 2, 2012 inspection, the FDA observed that approximately 83 vials of a bin of 321 vials of MPA from Lot #08102012@51 (shipped between August 17, 2012 and September 25, 2012) to contain a greenish black foreign matter. Seventeen vials from the same bin contained white filamentous material.

89. The FDA's sterility analysis of a sample confirmed the presence of "viable microbial growth" in all of the 50 vials tested. One vial showed fungal morphological features.

90. The FDA reported that NECC's formula worksheets state that the raw materials used to create their drug products are sterile, NECC's pharmacy director told the FDA that NECC uses non-sterile active pharmaceutical ingredients (API) and non-sterile raw materials to formulate preservative-free MPA, triamcinolone, and other injectable suspensions. The

inspection confirmed that the labeling for the MPA, API and other raw materials did not indicate that they were sterile.

91. NECC claimed that its "steam autoclave cycle" "sterilized" suspensions formulated with non-sterile materials. The FDA noted that NECC provided no documentation or evidence that this autoclave procedure worked. In fact, the FDA reported tarnish, condensation, and discoloration in the autoclaves. The FDA also observed puddles of water in the base of the autoclave chamber.

92. The FDA also reported that on at least 26 occasions between January 2012 and September 2012, NECC's internal environmental monitoring program recorded bacteria and mold in the clean rooms used to produce "sterile" drug products. This included at least 38 instances where the level of bacteria recorded was above the level where NECC was supposed to take action ("action level" or "action limit") and 18 instances where the level of mold reported was above NECC's action level. According to the FDA's director of manufacturing and product quality, an action limit is a threshold measurement of contamination "above what would typically be seen in a controlled sterile environment." Yet NECC took no action to investigate or correct this bacterial and mold contamination:

> *There was no investigation conducted by the firm when levels exceeded their action limits and there was no identification of the isolates. No documented corrective actions were taken to remove the microbial contamination (bacteria and mold) from the facility.*

93. Some of the petri dishes used to grow microbes present in environmental samples taken from windowsills, equipment, furniture, floors and other surfaces were "overflowing" with bacteria or fungi in sheets "very visible to the naked eye." The FDA also reported that samples taken from inside the hoods used for compounding (also inside the ostensibly clean rooms)

between January and September 2012 showed at least eight instances of bacterial and/or mold contamination. NECC did not investigate this contamination, did not identify the types of mold or bacteria growing in their ostensibly sterile hoods, nor did it investigate the impact of this contamination on any of the purportedly sterile products made in the hoods on the days the samples were taken. "[NECC] has no evidence that any corrective actions were taken to prevent contamination of the sterile drug products."

94. The FDA also observed that a plastic and mattress recycling facility next door produced dust and other airborne contaminants. NECC's HVAC units on the roof were about 100 feet from the recycling facility. Inside NECC, the FDA observed that dark particulate and white, filamentous substances covered the louvers of an HVAC return located behind the autoclave in the clean room.

95. The FDA also observed that the air-conditioning in the clean rooms was turned off overnight. This is not typical for a clean room, as temperatures need to be kept constant to minimize microbial growth.

96. The FDA also observed that a boiler located within 30 feet of the entrance to one of the "Prep Room[s]" was leaking water into puddles. The wet floor around the boiler was soiled with thick white debris and thick black granular material.

97. The mat at the entrance of the Prep Room was brown and soiled. In other words, it was filthy.

98. The FDA also observed cloudy discoloration on the barrier facing the ISO 6 Clean Room and metal surfaces of the pass through in the wall to the ISO 6 Clean Room. The metal ledge within the clean room contained reddish-brown and cloudy substances. And there were "dark, hair like discoloration" along the gasket and crevices located at the bottom edge of

the closed pass through installed within the wall of the ISO 6 Clean Room. NECC used ISO 6 Clean Room to formulate and fill sterile preparation, including MPA.

K. The Investigation Grows

1. FDA Confirms Other NECC Products Are Contaminated.

99. On October 15, 2012 the FDA issued an advisory that a patient may have acquired fungal meningitis from a different steroid injection, triamcinolone acetonide. In addition, the FDA reported a transplant patient with aspergillus fumigatus infection who received NECC cardioplegic solution during surgery. MDPH asked Massachusetts providers to contact any patients who received any injectable product, including opthalmis drugs or cardioplegia solutions prepared by NECC after May 21, 2012.

100. On October 18, 2012 the FDA confirmed the presence of fungal contaminates in sealed vials of MPA in a suspect lot prepared by NECC. The FDA also collected samples from sealed vials of completed product at Ameridose.

2. Board of Pharmacy Revokes Cadden, Chin and Conigliaro Pharmacy Licenses.

101. On October 22, 2012 the Board of Pharmacy and MDPH announced that Barry J. Cadden, Glenn A Chin, and Lisa Conigliaro Cadden are prevented from practicing as pharmacists, that it asked all three to surrender their pharmacist licenses immediately, and that if they did not voluntarily comply their license would be permanently revoked. According to MDPH, "[i]f the three pharmacists and NECC do not comply, the Board authorized staff to proceed with permanent revocation."

L. Subsequent Litigation.

102. Lawsuits alleging death or injury based on contaminated MPA and other contaminated drugs have been filed around the country. On February 12, 2013, the Judicial Panel

on Multidistrict Litigation issued an order under 28 U.S.C. § 1407 transferring various federal court proceedings to the United States District Court for the District of Massachusetts for coordinated pretrial proceedings.

V. FACTUAL ALLEGATIONS

103. For approximately 6 months prior to July 10, 2012, Decedent was a patient of and underwent the continuous medical care and treatment of the O'Connell Defendants in connection with his chronic pain due to, *inter alia*, his medical conditions of sacroiliac joint dysfunction, lumbrosacral pain and radiculopathy, peripheral neuropathy, and other related conditions of his lower back, right hip, and right leg arising out of a serious motor vehicle accident in April, 2009. At all times material herein, he was attended to, diagnosed and treated by the O'Connell Defendants.

104. The O'Connell Defendants and their employees, affiliates, and agents owed Plaintiff numerous duties including, without limitation, the following: to act as reasonable and prudent healthcare providers; and to ensure that the medical treatment, including drugs, that they administered to patients, including Plaintiff, was safe and effective.

105. On or about July 10, 2012, Defendant Cochran, under the supervision of Drs. O'Connell and/or Grover, at Dr. O'Connell's Pain Care Center and/or Dr. O'Connell's Pain Care Centers, Inc.'s facility, performed an injection procedure on Mr. Katz's right sacroiliac joint, during which procedure he was administered, according to his medical records, approximately 40 mg of NECC's Triamcinolone from one or more vials.

106. On or about August 7, 2012, Defendant Cochran, under the supervision of Drs. O'Connell and/or Grover, at Dr. O'Connell's Pain Care Center and/or Dr. O'Connell's Pain Care Centers, Inc.'s facility, performed an injection procedure on Mr. Katz's right sacroiliac joint,

during which procedure he was administered, according to his medical records, approximately 80 mg of NECC's Triamcinolone from one or more vials.

107. On or about September 25, 2012, Defendant Cochran, under the supervision of Drs. O'Connell and/or Grover, at Dr. O'Connell's Pain Care Center and/or Dr. O'Connell's Pain Care Centers, Inc.'s facility, performed an injection procedure on Mr. Katz's right sacroiliac joint, during which procedure he was administered, according to his medical records, approximately 60 mg of NECC's MPA from one or more vials. Upon information and belief, the MPA used during the procedure was drawn from vials that were part of the three lots of fungus-contaminated MPA vials that NECC recalled on or about September 26, 2012 due to fungal contamination traced back to it by the CDC following discovery of the fungal meningitis outbreak.

108. The O'Connell Defendants knew, or should have known, that the MPA they purchased acts as an immune system-suppressing agent, thus weakening the patient's, including Plaintiff's, natural ability to fight off pathogens that could possibly be included in the injection.

109. The O'Connell Defendants knew, or should have known, the importance of purchasing and administering safe and effective drugs to their patients, including Plaintiff.

110. The O'Connell Defendants knew, or should have known, that one of the best ways of ensuring that it injects safe and effective drugs directly into the joints and other vulnerable places of their patients, was to use only drugs approved by the FDA for the intended form of administration.

111. The use of NECC's drugs administered to the Plaintiff has not been approved by the FDA.

112. The O'Connell Defendants knew, or should have known, that NECC's drugs that it administered to the Plaintiffs had not been approved by the FDA.

113. The O'Connell Defendants knew, or should have known, that another way of ensuring that they administered safe and effective drugs directly into the bodies of their patients was to purchase such drugs from an FDA-regulated manufacturer.

114. The O'Connell Defendants knew, or should have known, that NECC was not an FDA-approved manufacturer.

115. Upon information and belief, the O'Connell Defendants ordered and purchased preservative-free MPA from NECC for significantly less than normal retail cost at a significant discount, at least $6.00 per vial or $480.00 per order and, as a result, knew or should have known that they were purchasing an inferior product.

116. NECC's cheaper, unregulated drugs were used by the O'Connell Defendants in lieu of commercially available drug products manufactured by FDA-approved manufacturers.

117. It is a violation of the laws of the United States and the Commonwealth of Massachusetts to sell compounded drugs in bulk and without a patient-specific prescription. NECC and the O'Connell Defendants violated these laws.

118. Rather than producing small quantities of its drugs on a per-prescription basis, NECC engaged in the illegal and risky process of producing and marketing very large quantities of its drugs at one time and not per prescription as required by the laws of the United States and the Commonwealth of Massachusetts.

119. The O'Connell Defendants knew, or should have known, that NECC engaged in the process of producing and marketing very large quantities of its drugs.

120. NECC acted as a wholesale distributor by selling very large quantities of its drugs to the O'Connell Defendants.

121. NECC engaged in the large-scale production and sale of its drugs without individual prescriptions in violation of the laws of the United States and/or Commonwealth of Massachusetts.

122. The O'Connell Defendants knew, or should have known, that NECC engaged in the large-scale production and sale of its drugs without individual prescriptions in violation of the laws of the United States and/or Commonwealth of Massachusetts.

123. Notwithstanding the foregoing knowledge, the O'Connell Defendants voluntarily purchased drugs for use on the Plaintiff on a wholesale basis from NECC without prescriptions.

124. Upon information and belief, the O'Connell Defendants never provided NECC with patient-specific prescriptions as required by law.

125. Under the laws of the United States and Commonwealth of Massachusetts, compounding pharmacists must ensure compliance with USP-NF standards (United States Pharmacopeial National Formulary).

126. NECC and its pharmacists did not comply with USP-NF standards.

127. The O'Connell Defendants knew, or should have known, that NECC was not compliant with USP-NF standards.

128. The O'Connell Defendants knew, or should have known, that another way of ensuring that safe and effective drugs are administered to their patients, including the Plaintiff, was to purchase such drugs from an accredited compounding pharmacy or purchase pharmaceuticals directly from pharmaceutical manufacturers regulated by the FDA.

129. NECC is not, and at all relevant times was not, accredited by the Pharmacy Compounding Accreditation Board ("PCAB") or any other similar organization, such as The Joint Commission, that offers independent assurance as to the quality and competence of compounding pharmacies that meet certain requirements.

130. The O'Connell Defendants knew, or should have known, that NECC was not an accredited compounding pharmacy.

131. There are accredited compounding pharmacies throughout the United States and, in fact, in New Hampshire, but the O'Connell Defendants chose not to purchase drugs from them, electing instead to buy drugs from an unaccredited, unregistered wholesale pharmacy for use in treating Decedent.

132. The O'Connell Defendants knew, or should have known, that another way of ensuring that safe and effective steroids are administered to their patients was to purchase drugs which contain preservatives.

133. The hazards, dangers and problems entailed in administering compounded drugs, and especially the use of preservative-free sterile preparations, were well known to the medical profession, including the O'Connell Defendants, and the subject of many articles and professional guidance documents.

134. NECC produced MPA administered to the Decedent, without preservatives.

135. The O'Connell Defendants knew, or should have known, that NECC produced drugs they administered to the Decedent without preservatives and, in fact, upon information and belief, specifically ordered preservative-free drugs from NECC.

136. The O'Connell Defendants knew or should have known that purchasing and utilizing preservative-free products, as was done here, increased the risk of contamination.

Because the vials contained no antimicrobial preservative, there was nothing to inhibit the growth of bacteria and fungus that were introduced into the drugs administered to the Decedent by the O'Connell Defendants.

137. Upon information and belief, the O'Connell Defendants knew or should have known that preserved MPA was available to them from a reputable pharmacy during the time the NECC preservative-free product was being shipped to its facilities and, as such, knew or should have known that such an option existed and utilized that option.

138. Upon information and belief, the O'Connell Defendants realized a more significant profit per injection using the NECC MPA than they would have using MPA from another, more reputable, compounding pharmacy.

139. Despite the increased risk of using preservative-free drugs, and of purchasing drugs not approved by the FDA, the O'Connell Defendants purchased the drugs it administered to the Decedent from unaccredited NECC for use in the Decedent's body.

140. The O'Connell Defendants knew, or should have known, that another way of ensuring that safe and effective drugs are administered to their patients, including the Decedent, was to ensure that such drugs are produced to the highest standards, including in a highly sterile environment.

141. While NECC is not regulated by the FDA, in 2011 the American Society of Health-System Pharmacists (ASHP) published Guidelines on Outsourcing Sterile Compounding Services (hereinafter "Outsourcing Compounding Guidelines"). At all relevant times, the O'Connell Defendants were subject to the Outsourcing Compounding Guidelines.

142. At all times relevant, the O'Connell Defendants failed to perform the following due diligence prior to purchasing sterile compounds from NECC, as recommended by the ASHP Guidelines on Outsourcing Sterile Compounding Services, including, but not limited to:

a. verify whether NECC's quality processes demonstrated that NECC was a reputable and safe supplier of sterile injectable compounds;

b. determine if NECC was an accredited compounding pharmacy;

c. at least once annually, unannounced, visit NECC's corporate offices and compounding facilities and confer with NECC's corporate, pharmacy and compounding staff;

d. determine whether NECC had any product liability lawsuits filed against it for preparations compounded;

e. determine whether there had ever been recalls of any of NECC's compounded preparations;

f. evaluate NECC's standard operating procedures and manuals;

g. evaluate NECC's pharmacist technician training;

h. evaluate NECC's policies and procedures for sterility testing;

i. evaluate examples of batch reports for product being considered for outsourcing;

j. evaluate examples of quality-control reports;

k. obtain and evaluate history of the results of all NECC accreditation or regulatory surveys conducted of NECC's sites, including copies of significant regulatory actions;

l. determine if NECC could provide documentation of the end-product testing processes used to determine that compounded sterile preparations are sterile and free of pyrogens and unintended particulate matter;

m. evaluate whether NECC could assure that each compounded sterile preparation was sterile and free of pyrogens and unintended particulate matter according to professional established and accepted quality monitoring data;

n. determine whether NECC performed nonviable and viable particle testing in primary engineering controls (e.g., laminar flow workbench, biological safety cabinet) and room air according to USP chapter 797 standards;

o. determine whether NECC performed routine surface microbiological and fungal environmental monitoring to minimize contamination;

p. determine whether NECC had a policy that required validation of new or changed facilities, equipment, processes, container types, for sterility and repeatability;

q. determine whether NECC met ASHP, NIOSH and USP chapter 797 guidelines for the handling of hazardous agents;

r. evaluate NECC's quality management program, specifically as it relates to facility cleaning and validation, staff training, and competency assessment;

s. evaluate NECC's risk assessment program to ensure that medication errors are not introduced by new or increased outsourced compounding activities; and

t. determine whether NECC had a history of disciplinary or punitive actions by any regulatory agency.

143. Upon information and belief, had the O'Connell Defendants followed the recommendations set forth in the Outsourcing Compounding Guidelines, they would have found NECC in the deplorable conditions set forth above, learned of its unsuitable, checkered history, prior reprimands, and problems and complaints related to its practices and products.

144. Despite the importance of the sterile nature of the drugs the O'Connell Defendants administered to the Decedent, NECC's facility and production processes were unsanitary and unsterile, and lacked adequate quality control measures.

145. The O'Connell Defendants knew, or should have known, that NECC's drugs and production processes were unsanitary and unsterile, and lacked adequate quality control measures.

146. NECC took large quantities of non-sterile ingredients and placed them into an aqueous mixture that then had to be rendered sterile.

147. NECC's process made its drugs unreasonably dangerous, high-risk compounds.

148. NECC competed in the medical marketplace on the basis of offering cheaper prices. Upon information and belief, NECC's cheaper pricing was a major factor in the O'Connell Defendants' decisions to purchase drugs from NECC, as opposed to from other FDA-regulated manufacturers of approved drugs.

149. Despite what the O'Connell Defendants knew, or should have known, concerning NECC, they chose to purchase the drugs they administered to the Decedent from NECC, which was an unaccredited, unsafe compounding pharmacy that: (a) produced its drugs in the same complex as a waste facility; (b) produced the drugs in bulk batches; (c) did not

properly sterilize the drugs; (d) did not operate with adequate quality control measures; (e) did not operate in a sterile environment; (f) did not have adequately representative samples of the drugs independently tested by an FDA-approved testing facility before releasing them for distribution; (g) did not comply with USP-NF standards; (h) violated several provisions of the law designed to protect their citizens from substandard and adulterated prescription drugs; and (i) contracted with a cleaning company that failed to adequately and non-negligently perform the work it was hired to do.

150. Despite what the O'Connell Defendants knew, or should have known, concerning NECC, they chose to purchase the drugs they administered to the Decedent from NECC, in part, to increase their profits at the risk of patient safety.

151. The O'Connell Defendants failed to inform their patients, including Decedent, that they were receiving a preservative-free or otherwise drug produced from a compounding pharmacy, much less a compounding pharmacy with the characteristics and problems as described in the preceding paragraphs.

152. The O'Connell Defendants failed to inform their patients, including Decedent, that they were receiving a preservative-free or otherwise drug that was not approved by the FDA. They also failed to inform the Decedent that the drugs were obtained via mail order from a pharmacy in Massachusetts that was neither inspected by the FDA nor was accredited by any valid accrediting body. Such information is objectively material information to a reasonable patient's decision to undergo a procedure using such medication.

153. On the contrary, upon information and belief, many if not all of the O'Connell Defendants failed to inform their patients, including Decedent, that the drugs obtained from

NECC and injected into him were not, in fact, the name brand drug produced by a FDA-regulated laboratory and/or generic drugs produced by a FDA-regulated laboratory.

154. At all relevant times, Decedent never received from the O'Connell Defendants a drug produced to the same high quality standards as name brand or generic drugs produced by FDA-regulated manufacturers and he was never informed of the O'Connell Defendants' choice to purchase the drugs administered to her from an unaccredited facility like NECC.

155. In connection with the O'Connell Defendants obtaining NECC's preservative-free drugs for its patients, including Decedent, the O'Connell Defendants either failed to take or negligently performed the reasonable and necessary due diligence and investigatory steps and measures necessary to vet, evaluate and determine the safety and quality of NECC's products, and in particular, determine if NECC could properly and suitably compound, package and provide sterile preservative-free drugs for use by the O'Connell Defendants in procedures on Decedent.

156. At all times and places pertinent to this action, the drugs that the O'Connell Defendants voluntarily purchased from NECC and then sold and provided to their patients, including Decedent, were contaminated with fungus, mold, and/or other contaminates, and, therefore, were unsafe and unreasonably dangerous.

157. As a direct and proximate result of the O'Connell Defendants' wrongful conduct, the Decedent was administered contaminated products by the O'Connell Defendants, causing him serious injuries, compromising his immune system, and ultimately leading to death.

VI. GENERAL ALLEGATIONS

158. Following his Triamcinolone injections on or about July 10, August 7, and his MPA injection on September 25, 2012, the fungus contaminated MPA caused Decedent to

sustain and suffer infection and injury to his body. Decedent suffered damages including, but not limited to, meningeal infection, unpleasant and disabling symptoms, headache, neck stiffness, memory loss, slurred speech, vomiting, nausea, fever, generalized pain, sensitivity, fatigue, malaise, parasthesis, and debility as a result of the infection; exacerbation and/or worsening of sacroiliac joint dysfunction, lumbrosacral pain and radiculopathy, peripheral neuropathy, and other related conditions of his lower back, right hip, and right leg arising out of his serious motor vehicle accident in April, 2009, complicated by infection; numerous medical appointments between October, 2012 and November, 2014 with various physicians including, but not limited to, infectious disease specialists and primary care physicians, during which he complained variously of these symptoms, and none of whom were able to definitively diagnose or treat said infection and symptoms; and ultimately, on November 15, 2014, cerebrovascular accident and coma, followed by a ten (10) day hospital admission, and death on November 25, 2014.

159. Plaintiff, both individually and through the Decedent, has suffered loss and damages including, but not limited to: (a) past and future medical bills; (b) lost wages and loss earning capacity; (c) pain and suffering; (d) emotional distress and loss of enjoyment of life; (e) enhanced compensatory damages; (f) punitive damages under Massachusetts law and as permitted by the MDL; (g) multiple damages plus attorney's fees and costs under New Hampshire law; (h) attorney fees and costs; (i) loss of consortium; and (j) all other damages permitted by law.

VII. CAUSES OF ACTION

COUNT I – NEGLIGENCE AND GROSS NEGLIGENCE AS PERMITTED IN THE MDL

160. Plaintiff hereby repeats, realleges, and incorporates by reference each and every factual allegation set forth in the preceding Paragraphs as though fully and completely set forth herein.

161. The O'Connell Defendants had a duty to provide Decedent with reasonable care and treatment.

162. The O'Connell Defendants had a duty to exercise reasonable care to ensure that the drugs they purchased in order to sell and administer to their patients, including Decedent, were purchased from drug companies that complied with the laws regarding pharmaceuticals.

163. The O'Connell Defendants had a duty to exercise reasonable care to ensure that the drugs they provided to their patients, including Decedent, were purchased from a company that made safe and effective drugs.

164. The O'Connell Defendants had a duty to exercise reasonable care to ensure that the drugs they provided to their patients, including Decedent, were purchased from a company that utilized proper quality control, safety, and sterility measures in order to minimize the possibility that the drugs would become adulterated or contaminated.

165. The O'Connell Defendants had a duty to exercise reasonable care to avoid administering contaminated drugs, or drugs they knew or should have known to be contaminated, to Decedent.

166. The O'Connell Defendants had a duty to obtain informed consent from Decedent for the procedure performed on Decedent, adequately and accurately describing to him the nature

of the procedure, as well as the risks of such procedure, including the drugs that were to be administered during such procedure.

167. The O'Connell Defendants had a duty to exercise reasonable care to ensure that their patients are not infected with diseases.

168. In this case, where the drug came from an unaccredited, mass producing, out-of-state, compounding pharmacy, unregulated by the FDA, the O'Connell Defendants had a duty to inform Decedent of the source of the drug and the dangers associated therewith.

169. The O'Connell Defendants had a duty to exercise reasonable care to train and supervise their employees and/or agents regarding safe drug purchasing/procurement, infection control processes and disease prevention.

170. The O'Connell Defendants breached their duties to Decedent in many respects, including, without limitation:

a. The O'Connell Defendants failed to provide Decedent with reasonable care and treatment;

b. The O'Connell Defendants failed to exercise reasonable and prudent care to ensure that the drug they purchased and provided to Decedent was made by NECC in compliance with all applicable pharmaceutical laws;

c. The O'Connell Defendants failed to exercise reasonable and prudent care to ensure that the drug they purchased and provided to Decedent were sold to them by NECC in compliance with all applicable pharmaceutical laws;

d. The O'Connell Defendants failed to know and understand the source and supply of the drug they provided to Decedent;

e. The O'Connell Defendants failed to use the appropriate, necessary and reasonable due diligence and investigatory steps and measures necessary to vet, evaluate and determine the safety and quality of NECC's drugs, and in particular, determine if NECC could properly and suitably compound, package and provide sterile preservative-free drugs for administration to Decedent;

f. The O'Connell Defendants failed to follow the reasonable ASHP *Guidelines on Outsourcing Sterile Compounding Services* which, had they followed, would have established that NECC's products were unsuitable for administration to the Decedent;

g. The O'Connell Defendants failed to exercise reasonable and prudent care to ensure that the drug they provided to Decedent was produced in sanitary, sterile conditions;

h. The O'Connell Defendants failed to properly inform Decedent that the use of the drug was not approved by the FDA;

i. The O'Connell Defendants failed to properly inform Decedent of the risks and dangers associated with the administration of the drug; and they failed to inform her that they had obtained the drug from NECC, a mass-producing, unaccredited, non-FDA regulated compounding pharmacy;

j. The O'Connell Defendants failed to exercise reasonable care to avoid administering to Decedent a preservative-free, adulterated, contaminated and/or unreasonably dangerous drug;

k. The O'Connell Defendants failed to conduct adequate due diligence regarding whether NECC was a reputable and safe supplier of sterile injectable compounds;

l. The O'Connell Defendants failed to visit NECC's facilities before procuring compounded drugs, and other medicines, from NECC;

m. The O'Connell Defendants failed to investigate and exercise sufficient due diligence before administering drugs procured from NECC, including failing to investigate or inquire concerning NECC's compounding practices, standard operating procedures, pharmacist training, and risk management protocols;

n. The O'Connell Defendants failed to determine whether NECC had a history of recalling compounded medications before procuring medicines from that company;

o. The O'Connell Defendants failed to investigate NECC's regulatory history with the FDA and/or the Massachusetts Board of Registration in Pharmacy before procuring drugs from NECC;

p. The O'Connell Defendants failed to determine whether NECC had a history of product liability suits before procuring medicines from that company;

q. The O'Connell Defendants failed to keep abreast of the dangers of sterile compounding;

r. Upon information and belief, the O'Connell Defendants purchased compounded drugs in bulk from NECC without using patient-specific individual prescriptions;

s. The O'Connell Defendants failed to appropriately store drugs purchased from NECC to reduce the risk of the growth of contaminants;

t. The O'Connell Defendants failed to adequately supervise and train the physicians, nurses, agents and employees who ordered, procured and/or administered drugs from NECC;

u. The O'Connell Defendants failed to implement policies and procedures that would prevent the procurement of purportedly sterile drugs from an out-of-state compounding pharmacy with a deplorable facility and sterility procedures, a checkered regulatory past, product recall problems, and a history of product liability suits;

v. The O'Connell Defendants administered drugs to Decedent without taking reasonable steps to ensure that those medicines were from a reputable supplier and were not contaminated with lethal pathogens;

w. The O'Connell Defendants failed to promptly notify Decedent that she was injected with potentially contaminated steroids and failed to recommend that she receive prompt treatment of their potential infections and other symptoms;

x. The O'Connell Defendants chose to purchase and administer preservative-free drugs despite having the option of purchasing and/or administering drugs containing preservatives;

y. The O'Connell Defendants failed in the performance of their various duties in that they permitted Decedent to be infected and/or failed to prevent him and numerous other patients from being infected by the tainted MPA and to

contract disease that they did not have prior to presenting to the O'Connell Defendants for treatment; and

z. The O'Connell Defendants failed to exercise reasonable care in such other manners as may be shown through discovery and at trial.

171. The physicians, physician assistants, nurses, agents, employees and representatives who decided to procure drugs from NECC and those who administered them to the Decedent were employees or agents of the O'Connell Defendants, and they were acting within the course and scope of their employment or agency. Accordingly, the O'Connell Defendants are liable for the consequences of said person's or persons' conduct pursuant to the doctrine of *respondeat superior*.

172. The negligence of the O'Connell Defendants proximately caused Decedent's injuries and distress.

173. The foregoing acts and omissions by the O'Connell Defendants went beyond mere thoughtlessness, inadvertence or error of judgment. The actions of the O'Connell Defendants did not meet even the most minimal diligence to ensure that they were not injecting contaminated, adulterated, tainted, and unreasonably dangerous drugs directly into the bodies of their patients, including Decedent.

174. The acts and omissions of the O'Connell Defendants constituted such utter disregard for the rights of others, and such utter disregard for prudence, that they amount to complete neglect of the safety of patients, including Decedent.

175. As permitted in the MDL, the acts and omissions of the O'Connell Defendants were a heedless and palpable violation of their legal duties respecting the life and rights of

Decedent and constitute gross negligence as they exhibited very great negligence, or the absence of slight diligence, or the want of even scant care.

176. As a direct and proximate result of the O'Connell Defendants' acts and omissions, Decedent suffered, *inter alia*, a meningeal infection, which caused him to suffer a compromised immune system, extreme pain, physical disability, emotional distress, and eventual cerebrovascular accident and death at age 29, as outlined herein.

177. The O'Connell Defendants' conduct set out above was wanton, malicious, or oppressive thus warranting the imposition of enhanced compensatory damages and/or punitive damages as permitted by the MDL.

WHEREFORE, Plaintiff demands judgment against the O'Connell Defendants, jointly and severally, on Count I of this Complaint, in an amount that will justly compensate for the damages, together with interest, costs and her attorney fees incurred in this action, all within the jurisdictional limits of this Court.

COUNT II – MEDICAL NEGLIGENCE

178. Plaintiff hereby repeats, realleges, and incorporates by reference each and every factual allegation set forth in the preceding Paragraphs as though fully and completely set forth herein.

179. It was then and there the duty of the O'Connell Defendants, acting by and through its agents and employees, to possess reasonable care and knowledge and to exercise the degree of care and skill as the average and prudent practitioner should under the same or similar circumstances.

180. The O'Connell Defendants had a duty to obtain the consent of the patient prior to providing treatment, and to inform the patient of the type of information regarding the treatment

and/or procedure or such risks and alternative alternatives as would the ordinary prudent physician under the same or similar circumstances.

181. The O'Connell Defendants had a duty to inform the Decedent of the risks of being injected with the preservative-free MPA manufactured by NECC.

182. Yet nevertheless, the O'Connell Defendants failed in the performance thereof when they failed to properly inform Decedent of the origin and nature of the MPA and the risks of being injected with the preservative-free MPA as set forth herein, and when they caused Decedent and numerous other patients to be infected by the tainted MPA and to sustain disease that she did not have before presenting to the O'Connell Defendants, and when they recklessly failed to supervise its employees and enact or enforce appropriate policies, procedures, and protocols regarding all aspects of infection control including, but not limited to, procurement and/or administration of injectable medication.

183. As a direct and proximate result of the O'Connell Defendants' acts and omissions, Decedent suffered, *inter alia*, a meningeal infection, which caused him to suffer a compromised immune system, extreme pain, physical disability, emotional distress, and eventual cerebrovascular accident and death at age 29, as outlined herein.

184. As a result of the of the O'Connell Defendants' acts or omissions as set out herein, the Decedent suffered injury which would not otherwise have occurred.

185. Decedent's injuries, complications, suffering, and death occurred as a proximate result of the negligence of the O'Connell Defendants.

186. The O'Connell Defendants' negligence caused, or partially contributed to Decedent's injuries, complications, suffering, and death.

187. The O'Connell Defendants' conduct set out above was wanton, malicious, or oppressive thus warranting the imposition of enhanced compensatory damages and/or punitive damages as permitted by the MDL.

WHEREFORE, Plaintiff demands judgment against the O'Connell Defendants, jointly and severally, on Count II of this Complaint, in an amount that will justly compensate for the damages, together with interest, costs and her attorney fees incurred in this action, all within the jurisdictional limits of this Court.

COUNT III – VIOLATION OF NEW HAMPSHIRE PATIENTS' BILL OF RIGHTS N.H.R.S.A. 151:21

188. Plaintiff hereby repeats, realleges, and incorporates by reference each and every factual allegation set forth in the preceding Paragraphs as though fully and completely set forth herein.

189. The O'Connell Defendants are subject to N.H.R.S.A. 151:21 (the New Hampshire State Patients' Bill of Rights) because they are physicians and/or a medical facility licensed by and operating in the State of New Hampshire.

190. Pursuant to N.H.R.S.A. 151:21(IV), "health care provider" is defined as:

> *any person, corporation, facility, or institution either licensed by this state or otherwise lawfully providing health care services, including, but not limited to, a physician, hospital or other health care facility, dentist, nurse, optometrist, podiatrist, physical therapist, or psychologist, and any officer, employee, or agent of such provider acting in the course and scope of employment or agency related to or supportive of health care services.*

191. N.H.R.S.A. 151:21 requires that the policy describing the rights and responsibilities of each patient admitted to a facility shall include, at a minimum, "the patient shall be free from emotional, psychological, sexual and physical abuse and from exploitation, neglect, corporal punishment and involuntary seclusion." N.H.R.S.A. 151:21(VIII).

192. The O'Connell Defendants violated Plaintiff's State rights by neglecting to ensure Decedent's safety and to provide safe and reasonable medical care, including, but not limited to, injecting Decedent with tainted drugs as set forth herein.

193. As a direct and proximate result of the O'Connell Defendants' violation of the State Patients' Bill of Rights, Decedent suffered, *inter alia*, a meningeal infection, which caused him to suffer a compromised immune system, extreme pain, physical disability, emotional distress, and eventual cerebrovascular accident and death at age 29, as outlined herein.

194. Defendant's actions were wanton, malicious, or oppressive, and undertaken with reckless indifference and disregard of the consequences, reckless indifference and disregard of the well-being and safety of the Plaintiff.

WHEREFORE, Plaintiff demands judgment against the O'Connell Defendants, jointly and severally, on Count III of this Complaint, in an amount that will justly compensate for the damages, together with interest, costs and her attorney fees incurred in this action, all within the jurisdictional limits of this Court.

COUNT IV – NEGLIGENCE PER SE (DIRECT LIABILITY)

195. Plaintiff hereby repeats, realleges, and incorporates by reference each and every factual allegation set forth in the preceding Paragraphs as though fully and completely set forth herein.

196. The O'Connell Defendants owed Decedent an elevated duty of care based on their obligation to provide protective care to their patients when the patients are unable to protect themselves, such as when they are receiving injections into their bodies.

197. Decedent was unable to protect himself against being injected and infected with the tainted MPA by the O'Connell Defendants.

198. The O'Connell Defendants failed to provide Decedent with a higher level of care and security required of them.

199. The O'Connell Defendants' acts or omissions in violation of RSA 151:21 constitute a per se breach of their duty of care.

200. As a direct and proximate result of the O'Connell Defendants' acts and omissions, Decedent suffered, *inter alia*, a meningeal infection, which caused him to suffer a compromised immune system, extreme pain, physical disability, emotional distress, and eventual cerebrovascular accident and death at age 29, as outlined herein.

201. Defendant's actions were wanton, malicious, or oppressive, and undertaken with reckless indifference and disregard of the consequences, reckless indifference and disregard of the well-being and safety of the Plaintiff.

WHEREFORE, Plaintiff demands judgment against the O'Connell Defendants, jointly and severally, on Count IV of this Complaint, in an amount that will justly compensate for the damages, together with interest, costs and her attorney fees incurred in this action, all within the jurisdictional limits of this Court.

COUNT V – RECKLESS INFLICTION OF EMOTIONAL DISTRESS – ENHANCED DAMAGES

202. Plaintiff hereby repeats, realleges, and incorporates by reference each and every factual allegation set forth in the preceding Paragraphs as though fully and completely set forth herein.

203. It was then and there the duty of the O'Connell Defendants, acting by and through their agents and employees, to refrain from engaging in extreme and outrageous conduct that recklessly causes severe emotional distress to another.

204. The O'Connell Defendants breached their duties to Decedent in many respects and as set out herein, including, but not limited to:

a. The O'Connell Defendants, upon information and belief, purchased compounded drugs in bulk from NECC without using patient-specific individual prescriptions;

b. The O'Connell Defendants failed to protect the Decedent from harm and to prevent him from being infected with diseases;

c. The O'Connell Defendants injected the Decedent with tainted MPA and caused him to suffer an infection;

d. The O'Connell Defendants failed to promptly notify Decedent that he was injected with potentially contaminated steroids and failed to recommend that he receive prompt treatment of their potential infections and other symptoms; and

e. The O'Connell Defendants failed to refrain from engaging in extreme and outrageous conduct that recklessly caused severe emotional distress to Decedent in such other manners as set out in the Complaint herein and/or may be shown through discovery and at trial.

205. As a direct and proximate result of the O'Connell Defendants' acts and omissions, Decedent suffered, *inter alia*, a meningeal infection, which caused him to suffer a compromised immune system, extreme pain, physical disability, emotional distress, and eventual cerebrovascular accident and death at age 29, as outlined herein.

206. Decedent's injuries and distress occurred as a proximate result of the recklessness and/or negligence of the O'Connell Defendants.

207. The O'Connell Defendants' conduct set out above was wanton, malicious, or oppressive thus warranting the imposition of enhanced compensatory damages and/or punitive damages as allowed by the MDL.

WHEREFORE, Plaintiff demands judgment against the O'Connell Defendants, jointly and severally, on Count V of this Complaint, in an amount that will justly compensate for the damages, together with interest, costs and her attorney fees incurred in this action, all within the jurisdictional limits of this Court.

COUNT VI - NEGLIGENT INFLICTION OF EMOTIONAL DISTRESS

208. Plaintiff hereby repeats, realleges, and incorporates by reference each and every factual allegation set forth in the preceding Paragraphs as though fully and completely set forth herein.

209. It was then and there the duty of the O'Connell Defendants to protect Decedent from harm and, acting by and through its agents and employees, to exercise reasonable care to ensure that its patients are not infected with diseases.

210. Yet, nevertheless, the O'Connell Defendants failed in the performance thereof in that they caused Decedent and numerous other patients to be infected by the tainted MPA and to contract disease that they did not have before presenting to the O'Connell Defendants for treatment.

211. As a direct and proximate result of the O'Connell Defendants' acts and omissions, Decedent suffered, *inter alia*, a meningeal infection, which caused him to suffer a compromised immune system, extreme pain, physical disability, emotional distress, and eventual cerebrovascular accident and death at age 29, as outlined herein.

212. Decedent's injuries and distress occurred as a proximate result of the negligence of the O'Connell Defendants.

213. The O'Connell Defendants' conduct set out above was wanton, malicious, or oppressive thus warranting the imposition of enhanced compensatory damages and/or punitive damages as allowed by the MDL.

WHEREFORE, Plaintiff demands judgment against the O'Connell Defendants, jointly and severally, on Count VI of this Complaint, in an amount that will justly compensate for the damages, together with interest, costs and her attorney fees incurred in this action, all within the jurisdictional limits of this Court.

COUNT VII – WILLFUL AND KNOWING VIOLATION OF CONSUMER PROTECTION ACT (N.H. R.S.A. 358-A, et seq.)

214. Plaintiff hereby repeats, realleges, and incorporates by reference each and every factual allegation set forth in the preceding Paragraphs as though fully and completely set forth herein.

215. O'Connell Defendants engaged in trade and commerce within the State of New Hampshire.

216. Pursuant to R.S.A. 358-A, et seq., the O'Connell Defendants' acts and/or omissions alleged herein constitute unfair competition, unfair and deceptive acts or practices, constitute false representations, and constitute the O'Connell Defendants failure to perform and fulfill its promises, representations, and obligations to their patients, including Decedent. Additionally, the O'Connell Defendants' acts and/or admissions offend public policy, are immoral, unethical, oppressive, and/or unscrupulous, and caused substantial injury to their patients, including Decedent.

217. As described herein, O'Connell Defendants represented to their patients, including Decedent, that the products administered had characteristics, uses and benefits that they did not have.

218. As described herein, O'Connell Defendants represented that their products were of a particular standard, quality and grade that they either knew or should have known was not of the standard, quality or grade described.

219. As described herein, O'Connell Defendants advertised, promoted, and otherwise offered their services to the general public, including Decedent, and represented that they were competent to provide medical care and other health care services in a safe manner and in accordance with the accepted standard of care among similar health care providers when it was and in accordance with the accepted standard of care among similar health care providers when it was not.

220. O'Connell Defendants failed to provide accurate disclosures of all material information before Decedent agreed to be injected with an NECC Contaminated Drug.

221. O'Connell Defendants willfully and knowingly failed to abide by regulations, laws and guidelines set forth to protect consumer safety, constituting a violation of the New Hampshire consumer protection statutes set forth herein.

222. O'Connell Defendants' willful and knowing withholding of important safety information and critical product information constitutes a violation of New Hampshire consumer protection statutes set forth herein.

223. O'Connell Defendants actively, knowingly, and deceptively concealed the product's dangerous properties and life-threatening risks of which they knew or should have known. This conduct evidences bad faith and unfair and deceptive practices.

224. O'Connell Defendants engaged in the conduct as described herein that created a likelihood of confusion and misunderstanding.

225. O'Connell Defendants engaged in the conduct as described herein that created a likelihood of causing injury to unknowing consumers, including Decedent.

226. O'Connell Defendants' conduct as described herein constituted unfair and deceptive acts and practices, including, but not limited to:

a. Misrepresenting the nature, quality, and characteristics about the products they sold and administered to Decedent;

b. Caused likelihood of confusion or misunderstanding as to the source, sponsorship, approval, or certification of products and/or services;

c. Represented services as having characteristics, ingredients, uses, and benefits that they did not have;

d. Represented that services were of a particular standard, quality or grade that they did not possess;

e. Advertised services with the intent not to deliver them;

f. Advertised services with the intent not to supply reasonably expectable public demand;

g. Unfairly violating regulations, laws and guidelines set forth to protect consumer safety;

h. Advertised, promoted, and otherwise offered their services to the general public, including Decedent, and represented that they were competent to provide medical care and other health care services in a safe manner and in accordance with the accepted standard of care among similar health care

providers when it was and in accordance with the accepted standard of care among similar health care providers when it was not;

i. Unfairly exposing unknowing consumers, including Decedent, to significant, unnecessary risk of harm and actual harm and injury; and

j. All other unfair and deceptive acts set forth herein.

227. The practices described herein are unfair because they offend public policy as established by statutes, the common law, or otherwise. Additionally O'Connell Defendants were unethical and unscrupulous, and caused substantial injury to consumers, including Decedent. O'Connell Defendants engaged in unconscionable actions and courses of action.

228. O'Connell Defendants willfully and knowingly engaged in the conduct described herein, which they knew was deceptive, in the course of business, trade and commerce, and had a deleterious impact on the public interest.

229. O'Connell Defendants are liable to Plaintiff for all statutory, direct and consequential damages, and fees and costs resulting from this breach, including multiple damages.

230. Decedent was injected with NECC Contaminated Drugs for personal use and thereby suffered ascertainable losses as a result of the O'Connell Defendants' actions in violation of the consumer protection laws.

231. Had O'Connell Defendants not engaged in the deceptive conduct described herein, Decedent would not have allowed for the administration of NECC Contaminated Drugs, and would not have incurred related medical costs, injury, compromised immune system, cerebrovascular accident, and death.

232. O'Connell Defendants engaged in wrongful conduct while at the same time obtaining, under false pretenses, money from Decedent for the NECC Contaminated Drugs that would not have been paid had O'Connell Defendants not engaged in unfair and deceptive conduct.

233. O'Connell Defendants have a statutory duty to refrain from unfair or deceptive acts or trade practices in the promotion and sale of the NECC Contaminated Drugs.

234. Had O'Connell Defendants not engaged in the deceptive conduct described above, decedent Chevy Katz would not have purchased and/or paid for NECC Contaminated Drugs, and would not have incurred related medical costs.

235. Defendants' actions, as complained of herein, constitute unfair competition or unfair, unconscionable or deceptive acts or trade practices in violation of N.H. R.S.A. 358-A:1 *et seq*.

236. Under the statutes listed above to protect consumers against unfair, deceptive, and unconscionable trade and business practices and false advertising as well as NH RSA 382-A:2, et seq., O'Connell Defendants are the suppliers, advertisers, and sellers, who are subject to liability under such legislation for unfair, deceptive and unconscionable consumer sales practices.

237. O'Connell Defendants violated the statutes that were enacted in New Hampshire to protect consumers against unfair, deceptive, and unconscionable trade and business practices and false advertising, by knowingly and falsely representing that the NECC Contaminated Drugs were fit to be used for the purpose for which they were intended, when, in fact, they were defective and dangerous, and by other acts alleged herein.

238. The actions and omissions of O'Connell Defendants alleged herein are uncured or incurable deceptive acts under the statutes enacted in New Hampshire to protect consumers against unfair, deceptive and unconscionable trade and business practices and false advertising.

239. Decedent relied upon O'Connell Defendants' misrepresentations and omissions in determining which product to use.

240. O'Connell Defendants' deceptive, unconscionable representations and material omissions to patients, physicians and consumers, constituted unfair and deceptive acts and practices.

241. By reason of the unlawful acts engaged in by O'Connell Defendants, and as a direct and proximate result thereof, Decedent has suffered ascertainable losses and damages.

242. As a direct and proximate result of O'Connell Defendants' violations of the consumer protection laws, Decedent suffered, *inter alia*, a meningeal infection, which caused him to suffer a compromised immune system, extreme pain, physical disability, emotional distress, and eventual cerebrovascular accident and death at age 29, as outlined herein, sustained economic losses and other damages, and is entitled to multiple damages, fees and costs, and statutory and compensatory damages, in an amount to be proven at trial.

WHEREFORE, the Plaintiffs demand judgment against O'Connell Defendants, on Count VII of this Complaint, in an amount that will justly compensate for the damages, together with interest, costs and his attorney fees incurred in this action, all within the jurisdictional limits of this Court.

COUNT VIII - FAILURE TO WARN

243. Plaintiff hereby repeats, realleges, and incorporates by reference each and every factual allegation set forth in the preceding Paragraphs as though fully and completely set forth herein.

244. A special relationship existed between the O'Connell Defendants and Decedent, which gave him a right to protection.

245. The O'Connell Defendants had a duty to protect Decedent against harm with regard to the tainted MPA.

246. The O'Connell Defendants provided high risk and unreasonably dangerous NECC Contaminated Drugs to patients, including Decedent, in the place of safe, medically acceptable drugs.

247. Yet, nevertheless, the O'Connell Defendants failed to inform their patients, including Decedent, that they were being administered an unsafe, unreasonably dangerous drug compounded by NECC rather than a high quality drug produced by an FDA regulated manufacturer.

248. Upon information and belief, the O'Connell Defendants prepared a Consent for Treatment Form. The form, which was presented to Decedent by the O'Connell Defendants, and which he read and relied upon when agreeing to accept treatment, failed to inform Decedent of the risks and benefits of the procedures before it was performed. When presenting the form to Decedent, the O'Connell Defendants knew that nobody on its behalf would be informing Decedent of the inferior and unreasonably dangerous nature of the NECC preservative-free drug that would be administered to him. O'Connell Defendants knew that if Decedent were informed

of the true nature of the NECC drugs, Decedent would decline treatment with NECC drugs, threatening the O'Connell Defendants' profits.

249. Despite the increased risk of using preservative-free drugs, and of purchasing drugs not approved by the FDA, the O'Connell Defendants purchased the drugs it administered to Decedent from un-accredited NECC for use in his body.

250. As a direct and proximate result of the O'Connell Defendants' acts and omissions, Decedent suffered, *inter alia*, a meningeal infection, which caused him to suffer a compromised immune system, extreme pain, physical disability, emotional distress, and eventual cerebrovascular accident and death at age 29, as outlined herein.

251. The O'Connell Defendants' conduct set out above was wanton, malicious, or oppressive thus warranting the imposition of enhanced compensatory damages and/or punitive damages as allowed by the MDL.

WHEREFORE, Plaintiff demands judgment against Defendants on Count VIII of this Complaint, in an amount that will justly compensate for the damages, together with interest, costs and her attorney fees incurred in this action, all within the jurisdictional limits of this Court.

COUNT IX - PRODUCT LIABILITY CLAIMS

252. Plaintiff hereby repeats, realleges, and incorporates by reference each and every factual allegation set forth in the preceding Paragraphs as though fully and completely set forth herein.

253. The MPA injected into Decedent's spine was compounded by NECC. NECC has filed a voluntary petition for bankruptcy in the United States Bankruptcy Court for the District of Massachusetts, In re: New England Compounding Pharmacy, Inc., Case No. 12-

19882-HJB. On July 24, 2013, the Bankruptcy Court ordered that with respect to certain claims, NECC was presently insolvent and has been insolvent at all times since the petition date.

254. The O'Connell Defendants procured the MPA injected into Decedent's spine from NECC.

255. NECC's product was defective and unreasonably dangerous when it left NECC's control because it was contaminated with lethal pathogens, and it was in substantially the same condition at the time the O'Connell Defendants injected it into Decedent's spine.

256. The O'Connell Defendants charged Decedent money for the MPA it sold, injected and administered to him.

257. The O'Connell Defendants acted as the seller or distributor of the MPA compounded by NECC when it sold and administered the methylprednisolone to Decedent.

258. The O'Connell Defendants were engaged in the business of selling MPA compounded by NECC.

259. The purpose and manner of the Decedent's use of the MPA was intended and reasonably foreseeable by the O'Connell Defendants.

260. Accordingly, the O'Connell Defendants are "sellers" as defined by New Hampshire law.

261. The O'Connell Defendants, as a "seller", had a duty to make inspections or tests that are reasonably necessary to see that the MPA was safe for its intended use and for any other reasonably foreseeable purpose.

262. New Hampshire law authorizes Plaintiff to prosecute product liability claims against the O'Connell Defendants as the seller of the MPA injected into Decedent's spine.

263. The MPA that the O'Connell Defendants injected into Decedent's spine was unreasonably dangerous and defective at the time it left the O'Connell Defendants' control because it was contaminated with lethal pathogens.

264. Specifically, the MPA was in defective condition and unreasonably dangerous at all relevant times, because it was unsafe for normal or anticipated handling.

265. The methylprednisolone sold, distributed, administered, and injected into Decedent's spine was neither merchantable, nor fit for the purposes for which it was produced and sold. Accordingly, the O'Connell Defendants breached their warranties, both express and implied, as stated in RSA 382-A:2-101 et seq., including their warranty of fitness for a particular purpose.

266. The O'Connell Defendants are strictly liable for the harms, losses, injuries, and damages caused by the unreasonably dangerous and defective MPA injected into Decedent's spine.

267. As a direct and proximate result of the O'Connell Defendants' acts and omissions, Decedent suffered, *inter alia*, a meningeal infection, which caused him to suffer a compromised immune system, extreme pain, physical disability, emotional distress, and eventual cerebrovascular accident and death at age 29, as outlined herein.

268. The O'Connell Defendants' conduct set out above was wanton, malicious, or oppressive thus warranting the imposition of enhanced compensatory damages and/or punitive damages as allowed by the MDL.

WHEREFORE, Plaintiff demands judgment against Defendants, jointly and severally, on Count IX of this Complaint, in an amount that will justly compensate for the damages,

together with interest, costs and his attorney fees incurred in this action, all within the jurisdictional limits of this Court.

COUNT X - NEGLIGENT MISREPRESENTATION

269. Plaintiff hereby repeats, realleges, and incorporates by reference each and every factual allegation set forth in the preceding Paragraphs as though fully and completely set forth herein.

270. The O'Connell Defendants negligently misrepresented facts, including but not limited to those related to the safety and fitness for use of the MPA it injected into Decedent's spine.

271. The O'Connell Defendants' negligent misrepresentations were made for the purpose of inducing the Decedent to act.

272. The O'Connell Defendants' misrepresentations were made with respect to facts that were material to the transaction.

273. The O'Connell Defendants' representations were not true.

274. Decedent reasonably and justifiably relied on the O'Connell Defendants' misrepresentations.

275. As a direct and proximate result of the O'Connell Defendants' acts and omissions, Decedent suffered, *inter alia*, a meningeal infection, which caused him to suffer a compromised immune system, extreme pain, physical disability, emotional distress, and eventual cerebrovascular accident and death at age 29, as outlined herein.

276. The O'Connell Defendants' conduct set out above was wanton, malicious, or oppressive thus warranting the imposition of enhanced compensatory damages and/or punitive damages as allowed for by the MDL.

WHEREFORE, Plaintiff demands judgment against Defendants on Count X of this Complaint, in an amount that will justly compensate for the damages, together with interest, costs and her attorney fees incurred in this action, all within the jurisdictional limits of this Court.

COUNT XI – BREACH OF CONTRACT

277. Plaintiff hereby repeats, realleges, and incorporates by reference each and every factual allegation set forth in the preceding Paragraphs as though fully and completely set forth herein.

278. The O'Connell Defendants had a contractual obligation to Plaintiff, through Decedent, by virtue of N.H.R.S.A. 151:21 and by way of their promise to provide safe and reasonable medical care and treatment to their patients including, but not limited to, to achieve the result of alleviating and/or reducing Decedent's pain, and not to infect him with a disease.

279. Nevertheless, the O'Connell Defendants breached their said contractual obligations as set out herein.

280. As a direct and proximate result of the O'Connell Defendants' acts and omissions, Decedent suffered, *inter alia*, a meningeal infection, which caused him to suffer a compromised immune system, extreme pain, physical disability, emotional distress, and eventual cerebrovascular accident and death at age 29, as outlined herein.

WHEREFORE, Plaintiff demands judgment against the O'Connell Defendants, jointly and severally, on Count XI of this Complaint, in an amount that will put the Plaintiff in the same position as she would have been in had the O'Connell Defendants fully performed the terms of their agreement and to justly compensate for the damages, together with interest, costs and her attorney fees incurred in this action, all within the jurisdictional limits of this Court.

COUNT XII – LOSS OF CONSORTIUM

281. Plaintiff hereby repeats, realleges, and incorporates by reference each and every factual allegation set forth in the preceding Paragraphs as though fully and completely set forth herein.

282. During part of his illness and at the time off his death, the Plaintiff was the wife of Decedent.

283. As a direct and proximate result of the O'Connell Defendants' acts and omissions, Decedent suffered, *inter alia*, a meningeal infection, which caused him to suffer a compromised immune system, extreme pain, physical disability, emotional distress, and eventual cerebrovascular accident and death at age 29, as outlined herein.

284. As a direct and proximate cause and result of Decedent's death, Plaintiff lost her familial relationship with her husband Chevy, including the loss of comfort, society, affection, guidance, and companionship with Chevy, and is entitled to recover those damages provided by RSA 556:12,II, as well as any and all other damages allowable under New Hampshire law.

VIII – PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for relief against all Defendants, in all Counts set forth above, as follows:

A. Compensatory damages, in excess of the amount required for federal diversity jurisdiction and in an amount to fully compensate Plaintiff for all her injuries and damages, both past and present;

B. Special damages, in excess of the amount required for federal diversity jurisdiction and in an amount to fully compensate Plaintiff for all of her injuries and damages, both past and present, individually, and to fully compensate the Estate for the injuries and

damages sustained by the Decedent, including but not limited to, past and future medical expenses, lost income, pain and suffering, death, and loss of enjoyment of life;

C. Exemplary damages;

D. Punitive damages as allowed by law;

E. Attorneys' fees, expenses, and costs of this action;

F. Loss of consortium damages, where appropriate, and where allowed by RSA 556:12,II or otherwise allowed under New Hampshire law;

G. Pre and post-judgment interest in the maximum amount allowed by law; and

H. Such further relief as this Court deems necessary, just, and proper.

IX. JURY DEMAND

Pursuant to Federal Rule of Civil Procedure 38(b), Plaintiff demands a trial by jury.

As discovery is ongoing, the Plaintiff expressly reserves the right to amend and/or supplement this Complaint for Damages and Demand for Jury Trial.

Respectfully Submitted,

SARAH A. KATZ, BOTH INDIVIDUALLY AND AS ADMINISTRATRIX OF THE ESTATE OF CHEVY KATZ, F/K/A CHEVY WILDE

By Her Attorneys,

RILEE & ASSOCIATES, P.L.L.C.

Date: July 9, 2015

By: /s/ Cyrus F. Rilee, III

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